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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,685	04/22/2005	Einar Moen	Q-84077	4835
23373	7590	02/10/2006	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			SINGH, SATYENDRA K	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/511,685

Applicant(s)

MOEN ET AL.

Examiner

Satyendra K. Singh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-14 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-14 and 25-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>04/22/05</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

Claims 1-10 and 15-24 are cancelled by applicant's amendments to the claims.

Claims 11-14 and 25-27 (group II) are pending in the application, and are being examined on their merits, herein.

### *Election/Restrictions*

Applicant's election **without traverse** of the invention of group II (claims 11-14 and 25-27) in the reply filed on December 16<sup>th</sup> 2005 is acknowledged. The invention of group I (claims 2-10 and 15-24) have been cancelled by the applicant's amendments to the claims.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-14 and 26-27 recite the limitation "**biomass deriving component**" in the body of the claims. There is insufficient antecedent basis for this limitation in the broader claim 11 that does not disclose any such "biomass deriving component". Appropriate correction is required.

Claims 13-14, and 26-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims recite the limitation of "**biomass deriving component**" in the ratios of sterile nutrients and mineral salts in the composition of growth substrate, which is confusing. It is not clear as to what this limitation of "biomass deriving component" means and as to what is the component

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derived from the biomass relative to which the weight ratio of "sterile nutrient" such as glucose, or nitrate and mineral salts are to be measured, on a dry mass basis. In the absence of any definition for the said limitation provided by the applicant in the instant disclosure, it is not clear as to what exactly the claimed invention is. Clarification is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11-12 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Patz et al (DD 290,917, IDS; see English translation provided, [U]).

Claims are directed to a **microorganism growth substrate** comprising a sterile nutrient composition **derived from the biomass** of a culture of bacteria **including** methanotrophic bacteria, further comprising at least one **sterile nutrient**, and **optionally** containing a **diluent**; wherein the **sterile nutrient** is selected from glucose, nitrate and mineral salts, and combinations thereof, and wherein the said **mineral salts** are selected from the group consisting of potassium, calcium, magnesium, sodium, molybdenum, iron, zinc, boron, cobalt, manganese and nickel compounds .

The term "**derived from**" or "derive" recited in the claim (to a person of ordinary skill in the art) means (see prior art [V], Online Merriam-Webster dictionary) "to take, receive, or obtain especially from a specified source or to obtain (a chemical substance) actually or theoretically from a parent substance", and in the absence of any explicit definition provided in the instant specification, the term has been taken by the examiner to include any bacterial biomass which can be used to arrive at the same composition.

Therefore, a biomass "derived from" the culture of any bacteria (that is suitable as a microorganism growth substrate) would also encompass the invention, as claimed.

Patz et al [U] teach a microorganism growth substrate comprising a sterile nutrient composition (chemical thermal hydrolysate; see Patz et al, page 3, substance of the invention, and page 5, first paragraph, and example 1, in particular) derived from the biomass of a culture of bacteria including methanotrophic bacteria (a methylotrophic bacteria such as *Methylobacterium rhodesianum* IMET 11401; see Patz et al, page 1, claims and page 3, substance of the invention, in particular) further comprising at least one sterile nutrient (such as methanol; see Patz et al, , and optionally containing a diluent (such as water; see Patz et al, example 1 and 2, pages 6 and 7, in particular). Patz et al also teach sterile nutrient medium for fermentation of bacteria containing nitrate and mineral salts and combinations thereof (such as iron, copper, magnesium, manganese, zinc, nickel, boron, calcium, potassium, sodium, cobalt; see Patz et al, page 7, in particular).

Per MPEP 2111.01, in the absence of any specific definition provided in the instant specification the examiner must give broadest reasonable interpretation to all the terms in the claims (*During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000); and It is only when the specification provides definitions for terms appearing in the claims that the specification can be used in interpreting claim language. In re Vogel, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970).*

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 11-12 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patz et al (DD 290,917, IDS; see English translation provided, [U]) in view of Koffas et al (US Patent, 6,689,601 B2, [A]) as supported by Arcangeli & Arvin [W].**

Claims are generally directed to a microorganism growth substrate comprising a sterile nutrient composition derived from the biomass of a culture of bacteria including **methanotrophic bacteria**, further comprising at least one sterile nutrient, and optionally containing a diluent; wherein the **sterile nutrient** is selected from glucose, nitrate and mineral salts, and combinations thereof, and wherein the said **mineral salts** are selected from the group consisting of potassium, calcium, magnesium, sodium, molybdenum, iron, zinc, boron, cobalt, manganese and nickel compounds .

The teachings of Patz et al [U] have been discussed above, and are further relied upon in the same manner. Patz et al teach the composition as claimed in a process for

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the production of biogenic flocculants resulting from the cultivation of bacteria by using the sterile bacterial biomass hydrolysate (produced by chemical and thermal hydrolysis) as a nutrient source to grow a new strain of methylotrophic bacteria (such as *Methylobacterium rhodesianum* IMET 11401; see discussion, supra). Patz et al also teach sterile nutrient medium for fermentation of bacteria containing **nitrate and mineral salts and combinations thereof** (such as iron, copper, magnesium, manganese, zinc, nickel, boron, calcium, potassium, sodium, cobalt; see Patz et al, page 7, in particular).

However, a composition (see instant claim 11) wherein the sterile nutrient composition consists of biomass obtained from the culture of **methanotrophic bacteria**, has not been explicitly disclosed by the referenced invention of Patz et al [U].

Koffas [A] teach a high growth methanotrophic bacterial strain (Methylomonas 16a, a mutant methanotrophic bacteria) capable of growth on a C1 carbon substrate (such as methane or methanol) that is particularly suitable as a production platform for the production of biomass (that can be used for the production of single cell protein, exopolysaccharides or carbohydrates, pigments, and for the production of wide range of food and feed products) using the said carbon sources (see Koffas, abstract, figure 1-5, summary of the invention, columns 3-5, and column 20, in particular). Koffas et al also teach the sterile nutrient composition such as nitrate and mineral salts and combination thereof (in the form of a growth medium; see Koffas, columns 26 and 27, the composition of solution 1, in particular) for the culture of Methylomonas 16a.

It would have been obvious to a person of ordinary skill in the art to modify the microorganism growth substrate composition of Patz et al [U] containing the biomass from a methylotrophic bacteria (in the process to produce biogenic flocculants as taught by patz et al) such that the sterile nutrient composition contains a biomass from a culture of methanotrophic bacteria (i.e. substituting the cultured bacterial biomass with another suitable bacterial strain known to have higher protein content; see Koffas, column 2, lines 6-9, in particular) as taught explicitly by Koffas [A] (in order to produce the desired biomass for various purposes such as single cell protein, carbohydrates or pigments) as explicitly disclosed by Koffas using carbon sources (such as methane and /or methanol) that are cheap and cost effective.

The person of ordinary skill in the art would have been motivated to make such modification in the composition of Patz et al [U] because Koffas [A] discloses the benefits of using a bacterial biomass especially the biomass of methanotrophic bacteria (as it is known that the microbial biomass produced by such bacteria is typically very high in protein content ~70-80% by weight; see discussion, supra) and thus in turn will provide a better nutrient source (when incorporated in the composition used in the process of Patz et al) for microbial growth as supported by the disclosure from Arcangeli & Arvin [W] wherein (during a modeling study involving the growth of a mathanotrophic bacterial biofilm) they conclude the fact that heterotrophs and other nitrifiers co-existed with methanotrophs in the biofilm, and the heterotrophic biomass grew on the soluble polymers formed by the hydrolysis of the dead biomass entrapped in the said biofilm which develops because of the presence of ammonia and other mineral nutrients



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available in the spent medium from methanotrophic bacteria (see Arcangeli & Arvin, page 177, abstract, in particular).

The person of ordinary skill would have had a reasonable expectation of success when substituting the biomass obtained from the culture of bacterial strain (i.e. from *Methylobacterium* spp. to *Methylomonas* 16a) in the composition of Patz et al, because Koffas explicitly teaches the processes involved in the culture and production of biomass from such a methanotrophic bacteria that can be used for a variety of purposes, and as a microbial growth substrate as taught by the combined disclosures of Patz et al and Arcangeli & Arvin. Given the benefits accrued by the use of biomass obtained from the culture of a methanotrophic bacteria (as disclosed by Koffas and Arcangeli & Arvin), a person of ordinary skill in the art would be motivated to substitute the bacterial strain used in the composition of Patz et al (with a methanotrophic bacterial strain such as *Methylomonas* 16a or *Methylococcus capsulatus*) to produce commercially useful biological end products, including single cell protein, carbohydrates, pigments, and flocculants.

*As per MPEP 2144.06, In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118*

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time this invention was made.

**Claims 11-14 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patz et al (DD 290,917, IDS; see English translation provided,**

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**[U]) in view of Koffas et al (US Patent, 6,689,601 B2, [A]) as applied to claims 11-12 and 25 above, and further in view of Atlas & Parks (Handbook of Microbiological Media, 1993 edition, [X].**

Claims (13-14 and 26-27) are directed to a microorganism growth substrate composition wherein the **glucose** is present in a dry mass basis weight ratio of 5:1 to 1:5, relative to the **biomass deriving component** (claim 13); wherein the **nitrate and mineral salts** are present in a weight ratio of 0.01:1 to 0.2:1, relative to the biomass deriving component (claim 14); the growth substrate as claimed in claim 13, wherein the glucose is present in a dry mass basis weight ratio of 2:1 to 1:2, relative to the biomass deriving component (claim 26); and the substrate as claimed in claim 14, wherein the nitrate and mineral salts are present in a weight ratio of 0.05:1 to 0.1:1, relative to the biomass deriving component (claim 27).

The teachings of Patz et al, Koffas (as supported by Arcageli & Arvin) have been discussed above, and are further relied upon in the same manner.

However, a microorganism growth substrate comprising a sterile nutrient composition obtained from a culture of bacteria containing methanotrophic bacteria, and further comprising sterile nutrient, such as **glucose**, and nitrate and mineral salts that are present in **a dry mass basis weight ratios** (as specifically recited in instant claims 13, 14, 26 and 27), is not explicitly disclosed by the combined disclosures of Patz et al, Koffas (as supported by Arcageli & Arvin).

Atlas & Parks [X] provides the detailed disclosure about various nutrient media compositions routinely used for the cultivation (on solid as well as liquid media) of methanotrophic and heterotrophic bacteria (see Atlas & parks, for various methanotrophic bacteria, pages 574-579; and for heterotrophs such as various lactic acid bacteria and *Lactobacillus* spp., pages 483-488, in particular). Atlas & Parks teaches the use of glucose as a sterile nutrient for use in various media compositions

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routinely used for cultivation of various microbial species (see Atlas & Parks, pages 576, 483-488, in particular), and also the use of nitrate and mineral salts (see Atlas & Parks, pages 574-575, in particular) in the cultivation of microorganisms (being especially useful in the cultivation of methanotrophic bacteria).

It would have been obvious to a person of ordinary skill in the art at the time this invention was made to modify the microorganism growth substrate composition of (see also discussion, supra) Patz et al (with the combined disclosures of Koffas and Arcangeli & Arvin) such that the growth substrate comprises a sterile nutrient such as glucose, nitrate and mineral salts, and combinations thereof as explicitly taught by Atlas & parks [X]. The person of ordinary skill would be motivated to modify the growth substrate composition (as taught by Patz et al, Koffas, and Arcageli & Arvin) because the sterile nutrient compositions containing glucose, nitrate and mineral salts have been routinely used in the cultivation of various microorganisms (methanotrophic as well as heterotrophic) as explicitly disclosed by Atlas & parks (see discussion, supra). One of ordinary skill in the art would have had a reasonable expectation of success when modifying the composition according to the disclosures of Atlas & Parks because Atlas & parks have explicitly taught the amounts, ratios and preparation of such growth media compositions that are useful in cultivation of various microorganisms.

Although, Atlas & Parks [X] do not explicitly teach a microorganism growth substrate composition wherein the sterile nutrient such as glucose, or nitrate and mineral salts are present in specific **dry mass basis weight ratio** (as recited in the instant claims 13, 14, 26 and 27) in relation to the biomass (obtained from the culture of

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methanotrophic bacteria, i.e. the "biomass deriving component"; see discussion supra) used in the invention as claimed, the use of specific ratios of such nutrients (alone as well as in combinations thereof) in relation to the biomass used in the composition would have been a routine matter of optimization to a person of ordinary skill in the art (As evident by the fact that the optimum amounts of sterile nutrient such as glucose, and nitrate and mineral salts are explicitly disclosed by the referenced invention of Patz et al, and Atlas & Parks; see discussions supra). The selection of specific ratios to be used of the nutrient components (in relation to the biomass used) in the claimed growth substrate composition clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that it is a routine procedure to optimized the ratios of ingredients for the culture of any given individual microorganism (relative to other components or nutrients used in the composition) in order to obtain an optimum yield of specific cultured product or biomass, in the instant case being biogenic flocculant (see Patz et al, supra).

Furthermore, given the fact that sterile nutrients such as nitrate and mineral salts have been used by Patz et al in the cultivation of *Methylobacterium* using the composition as claimed, it would have been a matter of routine optimization of the medium composition as well as of specific ratios of the sterile nutrient in relation to the biomass used to arrive at an optimum growth substrate composition. A holding of obviousness over the cited claims is therefore clearly required.

As per MPEP 2144.05 [R3], II. OPTIMIZATION OF RANGES - A. Optimization Within Prior Art Conditions or Through Routine Experimentation: *Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or*

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*temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).*

Thus, the invention as whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made.

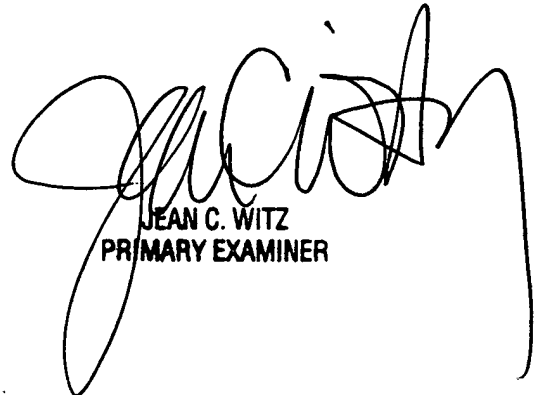
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF (with alternative Fridays being an off day).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Satyendra K. Singh  
Patent Examiner  
Art Unit 1651  
Phone: 571-272-8790



JEAN C. WITZ  
PRIMARY EXAMINER